IX. 510(k) Summary

MAR 8 2002

SUBMITTER:	DePuy AcroMed™, Inc. 325 Paramount Drive Raynham, MA 02767-0350 USA
CONTACT PERSON:	Karen F. Jurczak
DATE PREPARED:	December 07, 2001
PROPRIETARY NAME:	Conduit™ TCP Granules
CLASSIFICATION NAME:	Bone Graft Substitute Material, Bone Void Filler
PREDICATE DEVICE:	◆ Orthovita VITOSS (K994337) ◆ Pro Osteon 500R Resorbable Bone Graft Substitute (K990131)
INTENDED USE:	The Conduit™ TCP Granules are indicated for filling bone voids or defects of the skeletal system (such as the extremities, spine, and the pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Conduit™ TCP Granules is a bone graft substitute that resorbs and is replaced with bone during the healing process.
MATERIALS:	> 99% Beta-Tri Calcium Phosphate (β-TCP) $Ca_3(PO_4)_2$
PERFORMANCE DATA:	Physico-Chemical Characterization testing and animal testing were conducted.
DEVICE DESCRIPTION:	Conduit™ TCP Granules are a synthetic material, obtained after high-temperature ceramicization of a mixture of tribasic calcium phosphate. The Conduit™ TCP Granules are composed of interconnected pores occupying approximately 70% of the volume of the implant, and ranging in diameter between 1 and 600 µm. Conduit™ TCP Granules come in the form of irregular shaped granules having an average diameter between 1.5 and 3 mm inclusive.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2002

Mr. Frank Maas
Director, Regulatory Affairs
DePuy AcroMed
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K014053
Conduit™ TCP Granules
Regulatory Class: unclassified
Product Code: MQV
Dated: December 7, 2001
Received: December 10, 2001

Dear Mr. Maas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

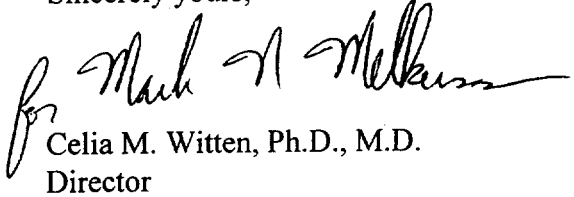
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

IV. Indications for Use

510(k) Number (if known): K014053

Device Name: Conduit™ TCP Granules

Indications For Use:

The Conduit™ TCP Granules are indicated for filling bone voids or defects of the skeletal system (such as the extremities, spine, and the pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Conduit™ TCP Granules is a bone graft substitute that resorbs and is replaced with bone during the healing process.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014053